



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

May 16, 2011

The Honorable Joseph R. Biden, Jr.  
President  
United States Senate  
Washington, DC 20510

Dear Mr. President:

The Animal Generic Drug User Fee Act of 2008 (AGDUFA) requires the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of its implementation of the Act. Please find enclosed the Fiscal Year (FY) 2010 report, which documents how FDA met each of the legal conditions specified in AGDUFA, allowing the Agency to continue collecting and spending animal generic drug user fees.

In addition, this report also provides the user fee collections and related expenses for FY 2010, and details the amounts carried forward at the end of the year that remain available to enhance the process for the review of abbreviated applications for generic new animal drugs and submissions. In FY 2010, FDA had net collections of \$4.5 million and spent \$4.7 million in animal generic drug user fees. During FY 2010, \$11.1 million was spent directly on the process for the review of abbreviated applications for generic new animal drugs.

The funds provided by AGDUFA are crucial to ensuring FDA has qualified personnel and the appropriate infrastructure to review new generic animal drugs in a timely manner.

Sincerely  
  
Kathleen Sebelius

Enclosure

**FY 2010 AGDUFA  
FINANCIAL REPORT**

**REQUIRED BY THE**

**ANIMAL GENERIC DRUG USER  
FEE ACT OF 2008**

**FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

## **Executive Summary**

The Animal Generic Drug User Fee Act of 2008 (AGDUFA) requires the Food and Drug Administration (FDA) to report annually on the financial aspects of its implementation of the Act. Required under AGDUFA, this report covers activities for fiscal year (FY) 2010.

AGDUFA specifies that the following three legal conditions must be satisfied each fiscal year in order for FDA to collect and spend AGDUFA user fees:

1. FDA's overall Salaries and Expenses Appropriation, excluding fees, must exceed FDA's overall FY 2003 Salaries and Expenses Appropriation, excluding fees and adjusted for inflation.
2. Fee collections must be specified in Appropriation Acts.
3. FDA must spend at least as much from appropriated funds for the review of abbreviated applications for generic new animal drug applications as it spent in FY 2008, adjusted for inflation.

This report explains how FDA met the three legal conditions in FY 2010. The statements and tables in the report provide data on generic new animal drug user fee collections and expenditures for FY 2010. In FY 2010, FDA collected \$4.5 million in generic new animal drug user fees, spent \$4.7 million in user fees for the review process, and carried a cash balance of \$2.2 million forward for future fiscal years.

AGDUFA implementation strategies facilitated the recruitment of new review staff in FY 2010. The generic new animal drug user fees and appropriations spent in FY 2010 supported 49 staff years, including salary and operational expenses to support the staff responsible for the process for the review of animal generic drug applications. In FY 2008, before the enactment of AGDUFA, FDA dedicated 26 full-time equivalents (FTEs) to this process. In FY 2011, FDA will spend user fees and appropriations to continue enhancing the review program and improve communications to meet the challenging performance goals associated with this program in FY 2011.

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ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS

## **BACKGROUND**

AGDUFA, Public Law 110-316, authorizes FDA to collect fees for certain abbreviated applications for generic new animal drugs, on certain generic new animal drug products, and on certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs.

AGDUFA was patterned in part after the Animal Drug User Fee Act (ADUFA). Under AGDUFA, three different kinds of user fees are established: (1) fees for certain types of abbreviated applications for generic new animal drugs (approximately 30 percent of estimated revenue); (2) annual fees for certain generic new animal drug products (approximately 35 percent of estimated revenue); and (3) annual fees for sponsors of generic animal drug applications and/or investigational submissions for a generic new animal drug (approximately 35 percent of estimated revenue). The aggregate fee revenue amount and amounts for each type of fee are set in statute, with provisions for adjustment. AGDUFA authorizes FDA to set fees for each fiscal year so that the total revenue FDA plans to receive in each category is estimated to equal the statutory amount, after adjustment for workload, if required.

AGDUFA requires FDA to submit two reports to Congress each fiscal year: 1) a performance report to be sent within 60 days of the end of the fiscal year, and 2) a financial report to be sent within 120 days of the end of the fiscal year. The FY 2010 AGDUFA Performance Report, that describes FDA's progress in meeting the goals referred to in AGDUFA, is being transmitted separately to Congress. This report is the FY 2010 AGDUFA Financial Report that addresses the implementation and use of animal generic drug user fees by FDA during the period of October 1, 2009 through September 30, 2010.

As required by AGDUFA, this report discusses the legal conditions that FDA must satisfy before it can collect and spend the animal generic drug user fees each year. In addition, this report presents summary statements of FY 2010 fee collections, carryover cash balances, obligations from fees, and total costs of the process for the review of animal generic drug applications from both fees and appropriations.

## MEETING THE LEGAL CONDITIONS FOR USER FEES IN FY 2010

AGDUFA imposes three legal conditions that must be satisfied in each fiscal year before FDA can collect and spend animal generic drug user fees. A summary of how each of these legal conditions was satisfied in FY 2010 is shown below. Detailed explanations and calculations are described in Appendix A.

**The first legal condition.** FDA's overall Salaries and Expenses appropriation (excluding user fees) must meet or exceed FDA's FY 2003 Salaries and Expenses appropriation (excluding user fees), including an adjustment for inflation. In FY 2010, FDA's budget authority appropriation for salaries and expenses was \$2,344,656,000 excluding user fees. FDA's FY 2003 Salaries and Expenses appropriation, excluding user fees and then adjusted for inflation, was \$1,640,978,301. Because \$2,344,656,000 is greater than \$1,640,978,301, the first legal condition was satisfied.

**The second legal condition.** The amount of user fees collected for each fiscal year must be specified in that year's Appropriation Acts. For FY 2010, The Agriculture, Rural Development, Food And Drug Administration And Related Agencies Appropriations Act (Public Law 111-80) specified that \$5,106,000 shall be derived from generic new animal drug user fees. The Appropriation Act also specified that the fees collected by FDA remain available to FDA until expended. Therefore, the second legal condition for FY 2010 was satisfied.

**The third legal condition.** User fees may be collected and used only in years when FDA spends at least as much from appropriated funds (excluding user fees) on the process for the review of abbreviated applications for generic new animal drug applications as it did in FY 2008 adjusted for inflation. This is referred to as the specified minimum in this report. Under AGDUFA, the condition is considered met if the total review expense funded by appropriations in any year is no more than 3 percent below the specified minimum. The specified minimum level for FY 2010 after the adjustment for inflation is \$5,711,874. In FY 2010, FDA obligated \$6,408,309 from appropriations, exclusive of user fees, for the review of abbreviated applications for generic new animal drugs. Because FDA spent more than the specified minimum amount from appropriations in FY 2010, the third legal condition was satisfied.

## USER FEE COLLECTIONS

AGDUFA specifies that the user fees shall be collected for certain abbreviated applications for generic new animal drugs upon their submission, and annual fees shall be collected for certain products and sponsors. The statute also specifies the amount FDA is allowed to collect for each of these categories, and how the fee rates should be adjusted in each fiscal year for increases in workload.

Under AGDUFA, fees collected and appropriated, but not spent by the end of a fiscal year, continue to remain available for FDA to spend in future fiscal years. The balances carried forward from year to year are described on page 7.

Table 1 provides a breakout of user fees collected by fee category during the past two fiscal years, and also reflects the amount of open receivables.

**TABLE 1**  
**STATEMENT OF GENERIC NEW ANIMAL DRUG USER FEE COLLECTIONS**  
**AND RECEIVABLES BY FEE SOURCES**  
**AS OF SEPTEMBER 30, 2010**

FEES COLLECTED	FY 2009	FY 2010
Application Fees	\$1,033,906	\$941,350
Product Fees	\$1,977,028	\$1,204,350
Sponsor Fees	\$2,088,151	\$1,864,687
<b>TOTAL COLLECTIONS</b>	<b>\$5,099,085</b>	<b>\$4,010,387</b>
FEES RECEIVABLE		
Product Fees	\$0	\$3,255
Sponsor Fees	\$43	\$27,068
<b>TOTAL RECEIVABLES</b>	<b>\$43</b>	<b>\$30,323</b>

User fee collections are reported in the year the fee was originally due—referred to as cohort years. For example, a fee originally due in FY 2009, even if it is received in FY 2010, is attributed to FY 2009 collections.

In FY 2010, FDA received a total of \$511,089 that was attributed to FY 2009 collections. Therefore, FDA increased its FY 2009 fee collections of \$4,587,996 reported last year to \$5,099,085 as of September 30, 2010.

The receivables for FY 2010 are from uncollected product and sponsor fees. After 90 days of attempting to collect the delinquent debt, FDA turns these receivables over to the Program Support Center (PSC) of the Office of the Secretary for collection.

Totals reported for each fiscal year are net of any refunds for that year. In order to ensure the quality of the information provided in financial reports, FDA will update prior year collections and receivables each year.

## USER FEE OBLIGATIONS

User fees are expended only for costs necessary to support the process for the review of abbreviated applications for generic new animal drugs, as defined in AGDUFA. Allowable and excludable costs for the process for the review of abbreviated applications for generic new animal drugs are described in Appendix D.

In FY 2010, FDA obligated \$4,736,800 from generic animal drug user fees. Table 2 provides a breakout of user fee obligations by expense categories during the past fiscal year.

**TABLE 2**  
**STATEMENT OF GENERIC NEW ANIMAL DRUG USER FEE OBLIGATIONS BY EXPENSE**  
**CATEGORIES**  
**AS OF SEPTEMBER 30, 2010**

Expense Category	FY 2009	FY 2010
Personnel Compensation and Benefits	\$1,669,902	\$3,196,041
Travel and Transportation	\$55,653	\$140,037
Rent	\$103,720	\$105,100
Communications	\$23,229	\$20,868
Contract Services	\$233,939	\$910,233
Equipment and Supplies	\$35,569	\$341,734
Other <sup>1</sup>	\$3,288	\$22,787
<b>Total Obligations</b>	<b>\$2,125,300</b>	<b>\$4,736,800</b>

<sup>1</sup> Other includes expenses from categories such as rent payments to others, printing & reproduction, and other miscellaneous expenses.

See the section TOTAL COST OF THE PROCESS FOR THE REVIEW OF ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS, on page 9, for more discussion on the total process costs for AGDUFA.

FDA is working to strengthen and expand its capacities to conduct efficient and timely reviews, and to ensure the safety and effectiveness of the generic new animal drugs. FDA dedicated 26 staff-years to the process for the review of animal generic drug applications in FY 2008, before AGDUFA was enacted.

In FY 2010, FDA dedicated a total of 49 full time equivalents (FTE) to the process for the review of animal generic drug applications. Animal generic drug user fees supported other operational expenses such as computers, furniture, supplies, rent, and other infrastructure needs to fully support these FTEs. During FY 2011, FDA expects to continue to enhance the review program necessary to meet the challenging performance goals associated with this program.

## CARRYOVER BALANCES

Under AGDUFA, fees collected, appropriated, and not obligated at the end of a fiscal year remain available to the FDA for use in future fiscal years. These funds are referred to as carryover balances. The operations in FY 2010 resulted in a reduction of the carryover balance by a total of \$214,759, for a year-end carryover balance of \$2,247,937.

**TABLE 3**  
**STATEMENT OF GENERIC NEW ANIMAL DRUG USER FEE COLLECTIONS,**  
**OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR**  
**AS OF SEPTEMBER 30, 2010**

Fiscal Year	Beginning Carryover	Net Collection	Obligation	Year-End Carryover
2009	-	\$4,587,996	\$2,125,300	\$2,462,696
2010	\$2,462,696	\$4,522,041	\$4,736,800	\$2,247,937
2011	\$2,247,937			

Numbers may not add due to rounding to the nearest dollar.

Please note that the balances in Table 3 reflect the cumulative cash from the beginning to the end of each fiscal year, and net cash collected during each fiscal year for all cohort years. The numbers do not include any accounts receivable. Therefore these numbers for FY 2009 and FY 2010 are different from the numbers on page 3, which reflect total new collections for the cohort years only.

## COLLECTIONS CEILINGS AND SURPLUS

Under AGDUFA, if the cumulative collections for FY 2009 through 2011, plus the amount of fees estimated to be collected in FY 2012, are in excess of the fee amounts specified in the Appropriations Act, the cumulative amount in excess of appropriations may be kept and used to reduce the fee rates when fees for FY 2013 are set. The following table depicts FY 2010 fee collections realized (the same as Total Collections in the table on page 3), collection ceilings specified in the Appropriations Act, and the cumulative difference.

**TABLE 4**  
**STATEMENT OF GENERIC NEW ANIMAL DRUG USER FEES COLLECTED, COLLECTIONS**  
**CEILING, AND AMOUNTS TO OFFSET FUTURE COLLECTIONS**  
**As of September 30, 2010**

Fiscal Year	Collections Realized	Collection Ceiling	Amount to Offset Future Collections
2009	\$5,099,084	\$4,831,000	\$268,084
2010	\$4,010,387	\$5,106,000	(\$1,095,613)
		<b>Total:</b>	<b>(\$827,529)</b>
<b>Balance to be Offset in a Subsequent Fiscal Year</b>			<b>\$0</b>

Additional FY 2010 cohort year fees collected subsequent to September 30, 2010 will be reported in the FY 2011 financial report.

**RESERVES AND BALANCE AVAILABLE FOR ALLOCATION**

Table 5 provides a summary of carryover balances as of September 30, 2010, and anticipated claims on those balances.

The only claim on the carryover balance is for prudent operations that require a reserve be kept aside for other potential refunds. For that purpose a total of \$100,000 is being set aside. That leaves a total of \$2,147,937 available for allocation. This is enough to fund estimated FY 2011 operations dependent upon user fee revenue for approximately 5 months.

**TABLE 5**  
**SUMMARY STATEMENT OF CARRYOVER BALANCE**  
**As of September 30, 2010**

Status of Carryover Funds	Amount
Reserve for Future Collection Offset	\$0
Reserve for Refunds	\$100,000
Available for Allocation	\$2,147,937
<b>TOTAL Carryover Balance</b>	<b>\$2,247,937</b>

**TOTAL COST OF THE PROCESS FOR THE REVIEW  
OF ANIMAL GENERIC DRUG APPLICATIONS**

Table 6 shows the costs for the review of abbreviated applications for generic new animal drugs during the past fiscal year by FDA organizational components. It depicts the full costs of the process for the review of abbreviated applications for generic new animal drugs paid from appropriations and user fees. The amounts are based upon obligations recorded at the end of FY 2009 and FY 2010.

**TABLE 6  
PROCESS FOR THE REVIEW OF ABBREVIATED APPLICATIONS FOR GENERIC NEW  
ANIMAL DRUGS  
TOTAL COST  
AS OF SEPTEMBER 30, 2010**

FDA Component	FY 2009	FY 2010
Center for Veterinary Medicine (CVM)	\$8,611,608	\$9,846,687
Field Inspection and Investigation (ORA)	\$565,977	\$403,145
Agency General and Administrative Costs	\$652,852	\$895,277
<b>Total Process Costs</b>	<b>\$9,830,437</b>	<b>\$11,145,109</b>
Obligations from Appropriations	\$7,705,137	\$6,408,309
Obligations from Generic New Animal Drug User Fees	\$2,125,300	\$4,736,800

A time reporting analysis is performed each year using data from FDA's CVM Activity Time Reporting (ATR) System to determine the percentage of time each organizational component within CVM devoted to activities that are included in the process for the review of abbreviated applications for generic new animal drugs, as defined in AGDUFA. This facilitates the calculation of process costs.

The field inspection and investigation are pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples that are counted for the review process for abbreviated applications for generic new animal drugs. FDA's ORA captures time spent in its field inspection and investigation by using the Field Accomplishments and Compliance Tracking System (FACTS).

Agency General and Administrative Costs increased in FY 2010 because the number of user fee funded FTE positions dedicated to the process for the review of animal drug applications went from 9 in AGDUFA's first year to 21 in FY 2010.

The development of the costs associated with the process for the review of abbreviated applications for generic new animal drugs is described in more detail in Appendix E.

## MANAGEMENT CHALLENGES FOR FY 2011

On August 14, 2008 the President signed Public Law 110-316, the AGDUFA. AGDUFA authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, on certain generic new animal drug products, and on certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs.

To meet the demanding review time goals established under AGDUFA in FY 2011, FDA plans to:

- Continue progress on management initiatives that include development of standard operating procedures for review processes, scientific policies for review staff, and implementation of a quality business system.
- Increase staffing necessary to help FDA meet AGDUFA review time goals.
- Develop and issue guidance to industry to explain current FDA thinking on the generic new animal drug review process.
- Provide training and educational opportunities for FDA staff to enhance the knowledge base of the review organization.
- Maintain the absence of backlog associated with abbreviated new animal drug applications (ANADAs) and for generic investigational new animal drug (JINAD) submissions.

FDA is committed to improving the efficiency, quality, and predictability of the new animal generic drug review process. We are dedicated to exploring new approaches and technologies that offer high quality and cost-effective improvements in FDA's review of ANADAs and other submissions. FDA looks forward to significant improvements in the animal generic drug review process that AGDUFA will help make achievable.

## CONDITIONS FOR ASSESSMENT AND USE OF FEES

The Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by AGDUFA, specifies three legal conditions that must be met in each fiscal year before FDA can collect and spend generic new animal drug user fees. A summary of the legal conditions has been introduced on page 2 of this report. This appendix provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2010.

In order to compare and determine whether the legal conditions are satisfied, FDA must calculate and incorporate adjustment factors.

Paragraph 741(k)(2) of the FD&C Act states the following definition:

The term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by –

- (A) for the purpose of subsection (f)(1), such Index for October 2002;
- and
- (B) for purposes of subsection (g)(2)(A)(ii), such Index for October 2007.

We refer to item (A) above as the first legal condition adjustment factor, and to item (B) above as the third legal condition adjustment factor. (The second legal condition does not have an adjustment factor associated with it.)

For **the first legal condition** adjustment factor above, the base month is October 2002. The consumer price index for October 2002 was 181.3. The consumer price index for October 2008, the October of the fiscal year preceding FY 2010, was 216.573. 216.573 divided by 181.3 equals 1.194556 (rounded to sixth decimal place). This is the adjustment factor for FY 2010 for the first legal condition (subsection (f)(1)).

For **the third legal condition** adjustment factor above, the base month is October 2007. The consumer price index for October 2007 was 208.936. The consumer price index for October 2008, the October preceding FY 2010, was 216.573. 216.573 divided by 208.936 equals 1.036552 (rounded to sixth decimal place). This is the adjustment factor for FY 2010 for the third legal condition (subsection (g)(2)(A)(ii)).

The **first legal condition** is found in section 741(f)(1) of the FD&C Act. It states:

Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2008 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the

amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

The first condition requires that FDA's Salaries and Expenses appropriation excluding user fees for FY 2010 must be greater than or equal to FDA's Salaries and Expenses appropriation excluding user fees for FY 2003 multiplied by the adjustment factor for inflation. FDA's Salaries and Expenses appropriation (excluding user fees) for FY 2003 was \$1,373,714,000 after the rescission. Multiplying this amount by the adjustment factor of 1.194556 (rounded to sixth decimal place) equals \$1,640,978,301.

In FY 2010, Congress appropriated \$2,344,656,000 to FDA for salaries and expenses, excluding user fees. Because the FY 2010 Salaries and Expenses appropriation is greater than the adjusted FY 2003 Salaries and Expenses appropriation (\$1,640,978,301) the first legal condition was met.

The **second legal condition** is described in section 741(g)(2)(A)(i) of the FD&C Act. It states that fees "shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year".

On October 21, 2009, the President signed the FY 2010, Agriculture, Rural Development, Food And Drug Administration And Related Agencies Appropriations Act, Public Law 111-80, which specified the collectable user fees amount for AGDUFA. That provision appropriated \$5,106,000 in generic new animal drug user fees. Therefore, the second legal condition was met.

The **third legal condition** is defined in section 741(g)(2)(A)(ii) of the FD&C Act. It states that fees:

shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of abbreviated applications for generic new animal drugs (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2008 multiplied by the adjustment factor.

The third condition requires a minimum spending from appropriations, excluding user fees, on the process of generic new animal drug review. The minimum spending from appropriations is the amount that FDA spent on the process for the review of abbreviated applications for generic new animal drugs in FY 2008, adjusted for inflation. FDA must spend no less than 3 percent below the minimum spending level from appropriations.

In accordance with AGDUFA, the base amount to be spent from appropriations for the process for the review of abbreviated applications for generic new animal drugs is the amount that FDA obligated from for the process for the review of abbreviated applications for generic new animal drugs in FY 2008, multiplied by the applicable adjustment factor, which for FY 2010 is 1.036552. In FY 2008 FDA obligated a total of \$5,510,456 for the process for the review of abbreviated applications for generic new animal drugs. Since the adjustment factor is 1.036552, FDA must spend at least \$5,711,874, exclusive of user fees, in FY 2010. In FY 2010, FDA obligated \$6,408,309 from appropriations for the process for the review of abbreviated applications for generic new animal drugs. Since the FY 2010 amount obligated from appropriations exceeds the specified minimum appropriation spending level, FDA met the third condition.

Table 7 shows the amounts FDA spent on the process for the review of abbreviated applications for generic new animal drugs from appropriations and user fees for FY 2010.

**TABLE 7**  
**OBLIGATIONS FOR THE PROCESS FOR THE REVIEW OF**  
**GENERIC NEW ANIMAL DRUG APPLICATIONS**  
**AS OF SEPTEMBER 30, 2010**

	Minimum Required from Appropriations in FY 2010	FY 2009	FY 2010
From Appropriations	\$5,711,874	\$7,705,137	\$6,408,309
From Fee Revenues		\$2,125,300	\$4,736,800
<b>Total Obligations</b>		<b>\$9,830,437</b>	<b>\$11,145,109</b>

**NUMBER OF FEES PAID IN FY 2010**

AGDUFA establishes three fee categories and sets fee revenues for each category. Based on the statutory revenues and estimated numbers of fees that would be paid in each category, FDA published the FY 2010 fee rates for all categories in August 2009<sup>1</sup>. The fee categories under AGDUFA are 1) Abbreviated Applications for Generic New Animal Drugs (\$75,000); 2) Generic New Animal Drug Product Fees (\$3,255); and 3) Generic New Animal Drug Sponsor Fees which range from \$27,025 to \$54,050 depending on the level of sponsor fee.

Table 8 summarizes the number and type of fees actually received in FY 2010 for cohort year 2010 in comparison to what the FDA estimated it would receive in FY 2010 when AGDUFA fees for FY 2010 were established in August 2010.

**TABLE 8  
NUMBERS OF GENERIC NEW ANIMAL DRUG USER FEES COLLECTED AND ANTICIPATED  
IN FY 2010  
AS OF SEPTEMBER 30, 2010**

<b>User Fee Category</b>	<b># of Fees Actually Collected in FY 2010</b>	<b># of Fees Anticipated in September 2009 when FY 2010 Fees were set</b>
Abbrev. New Animal Drug Applications	13	20.4
Products	370	549
Sponsors	34.5	33.075

<sup>1</sup> FDA published FY 2010 generic new animal drug user fee rates in the Federal Register notice – August 3, 2009 (74 FR 38434, <http://edocket.access.gpo.gov/2009/pdf/E9-18458.pdf>).

### WAIVERS AND REDUCTIONS GRANTED

AGDUFA directs FDA to waive or reduce fees for Minor Use or Minor Species (MUMS) applications. The waiver for MUMS is applied when the abbreviated application for a generic new animal drug is intended solely to provide for a minor use or minor species indication.

The tables below summarize the waivers and the reductions actions taken by FDA for fees payable in FY 2010, as well as the value of each granted. Please note that the waivers and the reductions granted in the tables below are for cohort year 2010 only.

**TABLE 9**  
**WAIVERS AND REDUCTIONS GRANTED AND USED BY FEE CATEGORY IN FY 2010**  
**AS OF SEPTEMBER 30, 2010**

Reason	Application & Supplement	Product	Sponsor	Total
Minor Use/Minor Species	0	1	2	3
<b>Total</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>

**TABLE 10**  
**VALUE OF WAIVERS AND REDUCTIONS GRANTED AND USED IN FY 2010**  
**AS OF SEPTEMBER 30, 2010**

Fee Category	Fee Rate	Number	Value
Applications	\$75,000	0	\$0
Products	\$3,255	1	\$3,255
Sponsors (100%)	\$54,050	0	\$0
Sponsors (75%)	\$40,538	0	\$0
Sponsors (50%)	\$27,025	2	\$54,050
<b>Total</b>		<b>3</b>	<b>\$57,305</b>

The waivers and the reductions presented in the table above were fees that were due and payable in FY 2010, and reflect revenue that would otherwise have been collected by FDA.

In FY 2010, FDA denied one sponsor fee waiver request.

**ALLOWABLE AND EXCLUDED COSTS FOR THE PROCESS  
FOR THE REVIEW OF ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS**

The FD&C Act, as amended by AGDUFA, Public Law No. 110-316, defines the process for the review of abbreviated applications for generic new animal drugs and the costs that may be included in that process. Fees may only be spent for activities that are included in this definition, although fee-generating activities are only a small subset of the activities that are included in this definition. Using the statutory definition and the methodologies described in Appendix E, the agency identified those activities that were applicable to the process for the review of abbreviated applications for generic new animal drugs.

Because over 96 percent of the amounts obligated by FDA each year are expended within two years, obligations represent an accurate measure of costs.

**AGDUFA RELATED COSTS**

**INCLUDED ACTIVITIES**

**[Section 741(k)(3)]** *The term ‘costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs’ means the expenses incurred in connection with the process for the review of abbreviated applications for generic new animal drugs for—*

**[Section 741(k)(3)(A)]** *officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;*

This includes costs for management and administrative services related to the process for the review of abbreviated applications, as well as costs for personnel development and training such as:

- scientific, clinical, and statistical training;
- managerial and other administrative training;
- policy/regulatory training;
- professional development (coursework, attendance at professional meetings, library resources); and
- site visit program for premarket reviewers.

**[Section 741(k)(3)(B)]** *management of information, and the acquisition, maintenance, and repair of computer resources;*

**[Section 741(k)(3)(C)]** *leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and*

**[Section 741(k)(3)(D)]** *collecting fees under this section and accounting for resources allocated for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

These sections include all forms of information management, facility rent, maintenance and repair, and infrastructure acquisitions in support of the process for the review of abbreviated applications for generic new animal drugs and in support of user fee collections and accounting.

**[Section 741(k)(10)(A)]** *The activities necessary for the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submissions.*

This encompasses, among other things, the review of the following types of information:

- with respect to ANADAs—original applications, pre- and post-market supplements, chemistry reports, reactivations, Veterinary Master Files, Public Master Files, and application-related correspondence
- with respect to JINADs—initial submissions, reauthorization requests protocols with or without data, and studies with or without data

Furthermore, the activities necessary for the review of ANADAs, supplemental ANADAs, JINADs, include:

- agency initiated action related to these applications and submissions;
- general ANADA and JINAD activities that do not directly relate to a pending submission, such as staff training and administrative support;
- administrative processing of these applications and submissions;
- maintenance and support of automated systems that track these applications and submissions; and
- quality assurance and quality control standards and policy development activities related to the review of these applications and submissions.

**[Section 741(k)(10)(B)]** *The issuance of action letters which approve abbreviated applications or supplemental abbreviated applications or which set forth in detail the specific deficiencies in abbreviated applications, supplemental abbreviated applications, or investigational submissions and, where appropriate, the actions necessary to place such applications, supplemental applications or submissions in condition for approval.*

This includes activities such as the issuance of deficiency letters, meetings with applicants to discuss such letters, and review of the responses.

**[Section 741(k)(10)(C)]** *The inspection of generic new animal drug establishments and other facilities undertaken as part of the Secretary's review of pending abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

**[Section 741(k)(10)(D)]** *Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

This includes monitoring of clinical and other research conducted in connection with the review of these applications and submissions.

**[Section 741(k)(10)(E)]** *The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

This includes activities such as development of drug-specific, cross-cutting, special control, program-related guidance, and Standard Operating Procedures.

**[Section 741(k)(10)(F)]** *Development of standards for products subject to review.*

This includes FDA's activities on national and international standards development for products subject to review.

**[Section 741(k)(10)(G)]** *Meetings between the agency and the generic new animal drug sponsor.*

This includes activities such as:

- informal consultation in person and via phone, mail, e-mail, and facsimile;
- meetings between FDA and sponsors, such as pre-submission conferences;
- use of Advisory Committees and outside experts in the review of ANADAs; and
- FDA sponsored conferences/workshops related to ANADAs.

**[Section 741(k)(10)(H)]** *Review of advertising and labeling prior to approval of an abbreviated application or supplemental abbreviated application, but not after such application has been approved.*

#### **EXCLUDED ACTIVITIES**

- Review of new animal drug applications and other pioneer submissions.
- Enforcement policy development.
- Post-approval surveillance and compliance activities.
- Post-approval activities relating to the review of advertising.

- Inspections unrelated to the process for review of abbreviated applications for generic new animal drugs.
- Research unrelated to the process for review of abbreviated applications for generic new animal drugs.

**DEVELOPMENT OF COSTS FOR THE PROCESS FOR  
THE REVIEW OF ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS**

**GENERAL METHODOLOGY**

The costs associated with the process for the review of abbreviated applications for generic new animal drugs are based on obligations recorded within FDA's CVM, ORA, and Office of the Commissioner (OC). These organizations correspond to the cost categories presented as follows:

<u>Cost Category</u>	<u>FDA Organization</u>
Costs for the Review of Abbreviated ANADAs, Supplemental Animal Generic Applications and Investigational Submissions	CVM
Costs for Field Pre-approval Inspection and Investigation	ORA
Costs for Agency General and Administrative Activities	OC

The costs were accumulated using time reporting systems in CVM and ORA, and were extrapolated for OC. Using the definitions of costs and activities included in the process for the review of abbreviated applications in the AGDUFA, as expanded in the discussion in Appendix D, the cost categories within each organization listed above were identified as parts of the abbreviated review process.

**CENTER COSTS**

Costs are accumulated for CVM in FDA's financial system in cost centers corresponding to the organizational components at the office level within CVM. Most CVM components involved in the generic new animal drug review process perform a mixture of activities—some included in the definition of the process for the review of abbreviated applications for generic new animal drugs, and some not included (see Appendix D). The activities involved in the process for the review of abbreviated applications for generic new animal drugs are categorized into three areas: 1) direct process activities, such as submission specific work; 2) indirect process and support activities, such as standard operating procedures and application review support; and 3) center-wide support activities. CVM's ATR System supports the allocations for all three areas.

**CVM's ATR**

CVM developed and implemented a total time reporting system as part of a multi-year Activity Based Costing initiative. The ATR has a robust Activity Dictionary developed

by CVM employees, describing the work “activities” of the Center employees. The system was implemented center-wide in October 2003. All CVM employees report their time in ATR.

Using the Activity Dictionary in conjunction with the definition of the process for the review of abbreviated applications for generic new animal drugs in AGDUFA, CVM was able to attribute activity time reported by its employees to direct and indirect process and support activities as distinguished from non-process activities. These activity definitions are consistent with the allowable costs for the process of the review of abbreviated applications for generic new animal drugs as detailed in Appendix D.

### **AGENCY-WIDE EXPENSES**

A number of agency-wide expenses are paid from the central accounts rather than from funds allocated to a specific center. These costs include rent for facilities that house CVM staff, telecommunications and utility costs, some computer equipment and support costs, facilities repair and maintenance costs, part of extramural and service contract costs, and costs of the Office of Shared Services which supports all FDA programs and activities. For these agency-wide costs that are chargeable to the center, we assumed that a percentage of them are chargeable to the process for the review of abbreviated applications for generic new animal drugs. That percentage was the amount of time reported for allowable activities (direct and indirect) in the center, as a percentage of total time reported for all center direct and indirect activities.

In support of the previous Administrations Management Agenda and Goal of “One-HHS”, FDA was requested to consolidate its administrative functions (including facilities, procurement, finance, equal employment opportunities, and information technology services) to carry out more efficient realignment of the resources which would provide high quality administrative services from a single organization. FDA created an Office of Shared Services in FY 2004. It combined the support responsibilities and resources previously located both in the centers and in OC, and ensured effective and efficient services in a competitive market environment. In this report resources expended by the Office of Shared Services in supporting the generic new animal drug review process are reported as if they were incurred in CVM, ORA, or OC.

### **FIELD INSPECTION AND INVESTIGATION COSTS**

ORA incurs all field inspection, investigation, and laboratory analyses costs. ORA costs are incurred in both district offices (the "field") and headquarters offices. Since FY 2000, ORA tracks the accumulated costs through a system called FACTS. FACTS is a time and activity tracking system that captures time spent in a variety of categories, including pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples, which are all part of the review process for generic animal drug applications.

Total direct hours reported in FACTS are used to calculate the total number of staff-years required by ORA to perform these activities. In addition to the direct time, an allocation of support time is also included to represent the work done by the ORA administrative and management personnel. The agency, then, multiplies the total number of staff-years used in the process for the review of animal generic drug applications by the average salary cost in ORA to arrive at ORA salary costs for work that is a part of the process for the review of abbreviated applications for generic new animal drugs as defined in AGDUFA. The final step is to allocate ORA obligations for operations and rent to the animal generic drug review process based upon the ratio of user fee related staff-years to total ORA staff-years. The following table summarizes the calculation of ORA costs for the review of abbreviated applications for generic new animal drugs for FY 2010.

**TABLE 11**  
**OFFICE OF REGULATORY AFFAIRS**  
**COSTS OF THE REVIEW PROCESS FOR ABBREVIATED APPLICATIONS FOR GENERIC**  
**NEW ANIMAL DRUGS**  
**AS OF SEPTEMBER 30, 2010**

<b>Cost Component</b>	<b>FY 2009</b>	<b>FY 2010</b>
Staff Years Utilized	3	2
ORA Average Salary and Benefits	\$107,401	\$108,065
Salary and Benefits (Staff Years times ORA Average Salary and Benefits)	\$322,203	\$216,130
Operating and Other Costs	\$243,774	\$187,015
<b>Grand Total</b> <b>(salary/benefits and</b> <b>operating/other costs)</b>	<b>\$565,977</b>	<b>\$403,145</b>

## AGENCY GENERAL AND ADMINISTRATIVE COSTS

The agency general and administrative costs are incurred in the FDA's OC. At the end of FY 2010, OC was comprised of the following offices:

- Immediate Office of the Commissioner
- Office of the Chief Counsel
- Office of the Chief of Staff
- Office of the Administrative Law Judge
- Office of Equal Employment Opportunity and Diversity Management
- Office of International Programs
- Office of Administration
- Office of Policy, Planning and Budget
- Office of Special Medical Programs
- Office of Legislation
- Office of the Counselor to the Commissioner
- Office of Women's Health
- Office of Foods
- Office of the Chief Scientist
- Office of International Programs
- Office of External Affairs

The OC costs applicable to the process for the review of generic new animal drugs were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human Services. The method uses the percentage derived by dividing total OC costs by the total FDA salary expenses (excluding benefits) after subtracting the salary expense (excluding benefits) from OC. That percentage is then multiplied by the sum of salaries (excluding benefits) applicable to the process for the review of abbreviated applications for generic new animal drugs in CVM and ORA to derive the applicable general and administrative costs.

Using this methodology, FDA dedicated \$895,277 in general and administrative costs to the animal generic drug review process in FY 2010. The costs are total costs obligated from appropriations and user fees. FDA strives to maintain a low overhead cost for the review process of the abbreviated applications for generic new animal drugs. General and administrative costs are approximately 8 percent of FY 2010 generic new animal drug review process costs.